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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,739	10/20/2000	Thomas Valentine McCarthy	1377-156P	3757

2292 7590 07/30/2002

BIRCH STEWART KOLASCH & BIRCH  
PO BOX 747  
FALLS CHURCH, VA 22040-0747

EXAMINER

TUNG, JOYCE

ART UNIT PAPER NUMBER

1637

DATE MAILED: 07/30/2002

17

Please find below and/or attached an Office communication concerning this application or proceeding.

# Advisory Action

Application No.

09/673,739

Applicant(s)

McCarthy et al.

Examiner

Joyce Tung

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Jul 5, 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see NOTE below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_

4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See the attached.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_

Claim(s) objected to: \_\_\_\_\_

Claim(s) rejected: claims 1-21 and 23

Claim(s) withdrawn from consideration: \_\_\_\_\_

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

10. ☐ Other: \_\_\_\_\_

Art Unit: 1637

1. The rejection of claims 1-21 and 23 under 35 U.S.C. §112, second paragraph in section 12 of the Office action mailed 2/5/2002 is withdrawn because of the amendment.
2. The rejection of claim 19 under 35 U.S.C. §112, second paragraph in section 6(d) of the Office action mailed 7/05/2001 is withdrawn because of the argument.
3. The rejection of claims 1-5, 8, 10-12, 14-16 and 20-23 remain rejected under the judicially created doctrine of obviousness-type double patenting as being obvious over claims 1, 2, 4-7, 12-13 and 15-19 of U.S. Pat. No. 5,952,176 in view of Chirikjian et al. (5,656,430).

Applicants argue that the teachings of McCarthy et al. do not disclose cleaving the DNA at the abasic site so as to generate an extendible upstream DNA fragment having a 3' hydroxyl terminus in which a template nucleic acid has partial or full sequence complementarity to the upstream fragment and analyzing resultant fragment. Although McCarthy et al. do not specifically disclose cleaving the DNA at the abasic site, McCarthy et al. disclose cleaving phosphate linkage at abasic sites and then analyzing the cleavage products (See column 73, claim 1) in which the method steps encompass "cleaving the DNA at the abasic site" (See the instant claim 1). Furthermore, although McCarthy et al. do not disclose generating an extendible DNA fragment having a 3' hydroxy terminus in which a template nucleic acid has partial or full sequence complementarity to the upstream fragment and analyzing resultant fragment (See the instant claim 1), McCarthy et al. disclose analyzing the cleavage products so as to identify target nucleic acid (See column 73, claim 1) in which the limitations of claim 1 of U.S. Pat. No. 5,952,176 encompass the limitations of the instant claim 1. Thus the rejection is maintained.

Art Unit: 1637

4. Claims 1-2 and 8-23 remain rejected under 35 U.S.C. § 103(a) over McCarthy et al. (WO 97/03210) in view of Chirikjian et al. (5,656,430).

The teachings of McCarthy et al. were discussed in section 3 above. Regarding the secondary reference, Applicants argue that Chirikjian et al. do not disclose the step I), ii) of the instant claim 1, and Chirikjian et al. disclose the glycosylase recognizes normal nucleic acid bases, not modified bases. However, Chirikjian et al. disclose that the glycosylase creates an abasic sugar (an AP site) at the point of mismatch which then is cleaved by an AP cleaving enzyme, such as endonuclease (See column 5, lines 24-33) and then the 3' hydroxyl terminus is extended (See fig. 2). This teachings suggest the limitations of step ii) of claim 1. Thus one of an ordinary skill in the art would have involved the probe as taught by Chirikjian et al. in the method of McCarthy because the method of Chirikjian et al. is efficient and sensitive by using the probe (See column 8, lines 47-50) with labeled nucleotides as the signal (See column 2, lines 48 and column 8, lines 47-49). Thus, it would have been prima facie obvious to carry out the method as claimed.

5. Claims 3-7 remain rejected under 35 U.S.C. § 103(a) over McCarthy et al. (WO 97/03210) in view of Chirikjian et al. (5,656,430) as applied to claims 1-2 and 8-23 above, and further in view of Dianov et al. (Molecular and Cellular Biology, 1992, Vol. 12(4), pg. 1605-1612).

Applicants argue that Dianov et al. merely disclose DNA repair mechanisms and the use of DNA polymerases to repair a damage site and fail to disclose at least either of steps I) or step

Art Unit: 1637

iv) of the present invention. As indicated in the Office action mailed, 7/05/2001, Dianov et al. disclose that the repair pathway of a dUMP residue in DNA involves uracil- DNA glycosylase and incision of the phosphodiester bond 5' to AP site by an AP endonuclease and baseless sugar-phosphate residue could be excised by a dRpase or a 5'-3'exonuclease to leave a hydroxy group at the 3' terminus (See pg. 1606, fig, 1) (as recited in claims 3-6) and then the polymerase step occur either after <sup>or</sup> before the excision step. The excision step is catalyzed usually by a DNA deoxyribophosphodiesterase (See pg. 1605, the Abstract) (as recited in claim 7). Thus, although Dianov et al. disclose DNA repair mechanisms and the use of DNA polymerases to repair a damage site, the teachings of the method steps of Dianov et al. read on the limitations of claims 3-7 as discussed above. Therefore, the rejection is maintained.

6. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

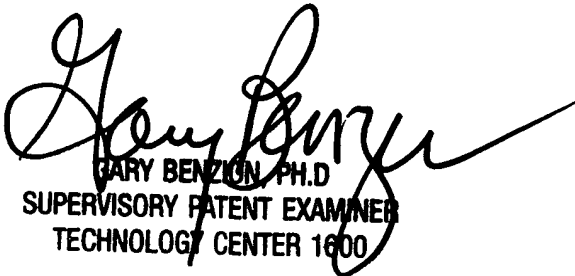
Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

Art Unit: 1637

7. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

July 18, 2002

  
GARY BENZON, PH.D.  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600